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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/436,060	11/08/1999	James T Kealey	014/002C	6093

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/436,060	KEALEY ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2005 and 07 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *29* is/are allowed.

6)☒ Claim(s) *27,28,30 and 31* is/are rejected.

7)☒ Claim(s) *32 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's Amendment and Remarks filed June 21, 2005 and November 7, 2005.

Claims 23-27 have been canceled. New claims 30-33 are acknowledged. Claims 27-29 have been amended.

Claims 27-33 are pending in the instant application.

Claims 27-33 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

Applicant's Amendment filed November 7, 2005 to comply with the requirements of 37 CRF § 1.121(c) is acknowledged.

Claim Rejections - 35 USC § 102

In the previous Office Action mailed December 22, 2004, claim 29 was rejected under 35 U.S.C. 102(e) as being anticipated by Villeponteau et al. [U.S. Patent No. 5,776,679]. **This rejection is withdrawn** in view of Applicant's Amendment to the claims filed June 21, 2005 to recite, "a polynucleotide consisting of". It is noted that the PCR primer disclosed by Villeponteau et al. *comprises* a sequence selected from SEQ

ID NOs. 2-14 of the instant invention, specifically SEQ ID NOs: 9-12. However, the PCR primer disclosed by Villeponteau et al. does not *consist of* a sequence selected from SEQ ID NOs. 2-14 of the instant invention.

Claim Rejections - 35 USC § 103

In the previous Office Action mailed December 22, 2004, claims 23, 25, and 26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Villeponteau et al. [U.S. Patent No. 5,776,679]. **This rejection is moot** in view of Applicant's Amendment to the claims filed June 21, 2005 to cancel claims 23, 25, and 26.

In the previous Office Action mailed December 22, 2004, claim 27 was rejected under 35 U.S.C. 103(a) as being unpatentable over Villeponteau et al. [U.S. Patent No. 5,776,679]. **This rejection is withdrawn** in view of Applicant's arguments filed June 21, 2005. Specifically, the Examiner agrees that Villeponteau et al. teach a PCR primer sequence comprising SEQ ID NOs: 9-12 of the instant invention, but provide no particular teaching to modify said primer.

After careful reconsideration of the claims, a new grounds of rejection is presented as detailed below:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27, 28, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villeponteau et al. [U.S. Patent No. 5,776,679] in view of Skerra, A. (Nucleic Acids Research 1992 Vol. 20:3551-3554).

Claim 27 is drawn to a polynucleotide comprising a sequence of at least 7 nucleotides that specifically hybridizes to a first nucleotide sequence within an accessible region of the RNA component of human telomerase (hTR), but does not hybridize to a second nucleotide sequence within a template region of the hTR, wherein the accessible region is selected from the group consisting of nucleotides 137-196, nucleotides 290-319, and nucleotides 350-380 of SEQ ID NO:16, wherein the polynucleotide comprises a nucleotide analog or an non-naturally occurring nucleotide linkage selected from phosphorothioates, phosphoramidates, methyl phosphonates, chiral-methyl phosphonates, 2-O-methyl ribonucleotides and peptide-nucleic acids, and wherein the polynucleotide is effective to inhibit the synthesis of telomeric DNA by telomerase. Claim 28 is drawn to the same invention as claim 27, with the further limitation, wherein the polynucleotide sequence is selected from SEQ ID NOs: 2-14 of the instant invention. Claim 30 is dependent on claim 28 and includes all the limitations of claim 28 with the further limitation, wherein said polynucleotide comprise a sequence

of at least 7 nucleotides that specifically hybridizes to a first nucleotide sequence within an accessible region of the RNA component of human telomerase (hTR), said accessible region being nucleotides 137-198 of SEQ ID NO:16. Claim 31 is dependent on claim 30 and includes all the limitations of claim 28 with the further limitation, wherein said accessible region being nucleotides 137-166 of SEQ ID NO:16.

Villeponteau et al. teach antisense expression plasmids prepared by PCR amplification of the RNA component cDNA using the following primer:

5'-GTTTGCTCTAGAATGAACGGTGGAAG-3' (see SEQ ID NO:23). This PCR primer is reverse complementary to nucleobases 145-170 SEQ ID NO:16 of the instant invention. It is noted that the PCR primer disclosed by Villeponteau et al. comprises SEQ ID NOs: 9-12 of the instant invention. It is further noted that the reverse complimentarity between the PCR primer disclosed by Villeponteau et al. and nucleobases 145-170 of SEQ ID NO:16 is contiguous as it contains no mismatches. Given this high degree of complementarity, the PCR primer disclosed by Villeponteau et al. meets the structural limitations of the claimed invention and would be expected to "specifically hybridize" to the accessible region of nucleotides 137-196 and 137-166 of SEQ ID NO:16 as claimed since the instant specification at page 10 lines 19 and 20 teaches "a polynucleotide "specifically hybridizes" to a target polynucleotide if the polynucleotide hybridizes to the target under stringent conditions". It is noted that the instant specification at page 10, lines 20-26 describes "stringent conditions" to be generally "the temperature and ionic conditions used in nucleic acid hybridization". Accordingly, the PCR primer disclosed by

Villeponteau et al. would specifically hybridize to the accessible region of nucleotides 137-196 and 137-166 of SEQ ID NO:16 as claimed.

The burden of establishing whether the prior art primer has the further function of inhibiting the synthesis of telomeric DNA by telomerase as instant claimed falls to Applicant. See (*In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977): "Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product... Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted]. See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2122 citing *In re Fitzgerald* 205 USPQ 594. 596, (CCPA 1980), quoting In re Best 195 USPQ 430 as per above. Therefore, it falls to Applicant to determine and provide evidence that the PCR primer disclosed by Villeponteau et al. would or would not have the additional functional limitation of inhibiting the synthesis of telomeric DNA by telomerase under generally any assay condition.

Villeponteau et al. do not teach the polynucleotide sequence comprises a modification, including a nucleotide analog or non-naturally occurring nucleotide linkage.

Skerra, A. teaches phosphorothioate-modified primers improve the amplification of DNA sequences by DNA polymerase with proofreading activity (see Abstract). Skerra, A. teaches the introduction of single phosphorothioate bond at the 3' termini of the PCR primer protects the oligodeoxynucleotide from exonuleolytic attack.

It would have been prima facie obvious to one of ordinary skill in the art at the time of filing to make a polynucleotide comprising a sequence of at least 7 nucleotides that specifically hybridizes to an accessible region of the RNA component of human telomerase (hTR), wherein the accessible region is nucleotides 137-196 of SEQ ID NO:6 as taught by Villeponteau et al. One of ordinary skill in the art would have been motivated to modify the polynucleotide to include a phosphorothioate linkage, for example, since Skerra et al. teach the introduction of single phosphorothioate bond at the 3' termini of the PCR primer protects the oligodeoxynucleotide from exonuleolytic attack. One of ordinary skill in the art would have expected success at modifying the polynucleotide because Skerra, A. taught the successful design of a phosphorothioate-modified primer that improves the amplification of DNA sequences by DNA polymerase with proofreading activity.

Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time of filing.

Conclusion

Claims 32 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the

limitations of the base claim and any intervening claims. Claims 32 and 33 are considered free of the prior art since the prior art does not teach or fairly suggest a polynucleotide comprising a sequence of at least 7 nucleotides that specifically hybridizes to a first nucleotide sequence within an accessible region of the RNA component of human telomerase (hTR), but does not hybridize to a second nucleotide sequence within a template region of the hTR, wherein the accessible region is selected from the group consisting of nucleotides 290-319 or nucleotides 350-380 of SEQ ID NO:16, wherein the polynucleotide comprises a nucleotide analog or an non-naturally occurring nucleotide linkage selected from phosphorothioates, phosphoramidates, methyl phosphonates, chiral-methyl phosphonates, 2-O-methyl ribonucleotides and peptide-nucleic acids, and wherein the polynucleotide is effective to inhibit the synthesis of telomeric DNA by telomerase.

Allowable Subject Matter

Claim 29 is allowable. Claim 29 is considered to be free of the prior art since the prior art does not teach or fairly suggest a polynucleotide consisting of a sequence of selected from SEQ ID NOs: 2-14.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg
January 23, 2006

SEAN McGARRY
PRIMARY EXAMINER
1635